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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/084,578 | 02/27/2002 | James L. DiGuiseppi | 9250-29 | 6023 |

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bioMerieux, Inc.
Patent Department
100 Rodolphe Street
Durham, NC 27712

| EXAMINER | |
|---|---|
| BEISNER, WILLIAM H | |
| ART UNIT | PAPER NUMBER |
| 1797 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/084,578 | DIGUISEPPI ET AL. | |
| | Examiner | Art Unit | |
| | William H. Beisner | 1797 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-5,7,9,11-15,17,18,20,21 and 29-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,9,11-15,17,18,20,21 and 29-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/24/2007 has been entered.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-5, 7, 9, 11, 12, 14, 15, 17, 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (US 4,215,198) in view of Calandra et al.(US 5,094,955) alone or alternatively further in view of Friedman et al.(US 4,829,005).

The reference of Gordon discloses a filtration and detection device that includes a container (11, 111) defining a chamber and having an inlet (43, 143) and an outlet (31, 131) in fluid communication with the chamber. The device includes a filter (23, 123) for filtering fluids and is mounted between the inlet (43, 143) and outlet (32, 131).

While the reference of Gordon discloses adding culture medium to the filter chamber and detecting color or turbidity changes for determining the presence of microorganisms in the sample fluid (See column 1, line 65, to column 2, line 6, and column 4, lines 40-56), claims 1 and 14 differ by reciting that the device includes a sensor mounted in the chamber wherein the sensor is positioned at an opposite end of the chamber from the filter.

The reference of Calandra et al. discloses that it is known in the art to mount a growth detection sensor (2) within a sealed culture vessel (1). The reference discloses that using the sensor is advantageous over conventional turbidity and/or color change detections because errors resulting from the presence of interfering materials in the sample can be reduced (See column 2, lines 20-45).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a sensor as taught by the reference of Calandra et al. in the container of the primary reference for the known and expected result of increasing the detecting efficiency within the detection device resulting from the use of the sensor of Calandra et al.

If the vessel of Gordon is considered to not be sealed in a manner adequate to be used with the sensing device of Calandra et al., the reference of Friedman et al. is cited to evidence that it is known in the art of sterility testing to construct the filtration device or container in a gas-tight manner so as to avoid contamination (See column 2, lines 14-26; column 8, lines 9-34).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the filtration device of the reference of Gordon in a gas-tight manner, if not inherent, for the known and predictable result of preventing contamination of the interior of the container and/or surrounding environment in which the container is employed.

With respect to the location of the sensor, the reference of Calandra discloses that the sensor can be positioned on the bottom of the container or in the sealing means of the container (See column 3, lines 61-68).

As a result, it would have been obvious to one of ordinary skill in the art to determine the optimum location for the sensor within the container while ensuring that the sensor is visible from outside the container. Specifically, in view of the teaching of Calandra, it would have been obvious to one of ordinary skill in the art to position the sensor on the cap (15, 115) of the device of Gordon. Note, in an already known device, the rearrangement or placement of parts that does

not alter the operation of the device is not a patentable distinction (See In re Kuhle, 526 F.2d 553, 188 USPQ7 (CCPA 1975). The configuration resulting from the teachings of Gordon and Calandra would result in a device wherein the sensor is parallel to and against an end wall of the chamber and wherein the chamber is transparent such that the senor can be detected through the chamber.

With respect to claims 2 and 14, the filter is a microporous filter.

With respect to claims 3 and 15, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum filter configuration while maintaining the required microorganism removal from the sample fluid flowed through the device.

With respect to claims 4, 5 and 7, the disclosed use of the sensor of the reference of Calandra et al. meet the limitations recited in claims 4, 5 and 7.

With respect to claims 1, 9 and 14, the containers in the references of Gordon and Calandra et al. are transparent.

With respect to claims 11 and 12, while not specifically disclosed by the reference of Gordon, it would have been obvious to one of ordinary skill in the art to provide the container with a removable cap and o-ring for the known and expected result of providing access to the interior of the container for removing the filter, if desired, while maintaining an air-tight seal.

With respect to claim 17, in the absence of a showing of criticality and/or unexpected results, it would have been well within the purview of one of ordinary skill in the art to determine the optimum volume of container to employ while maintaining the efficiency of the filtering and detection system.

With respect to claim 18, the container is made of plastic (See column 5, lines 21-23).

With respect to claim 21, the reference of Calandra et al. discloses the use of a measuring apparatus (5) to detect the measurable property of the sensor (2).

With respect to claims 29, 32, 39 and 40, the modified device as discussed above would be capable of being positioned in the recited operative position. Note statements of intended use carry no patentable weight in apparatus-type claims.

With respect to the claimed fixed end wall and continuous closed surface of claims 30, 31, 33, 34 and 37, the reference of Gordon discloses that the use of the lid is not required when operating the device (See Figures 4 and 5 and related disclosure). As a result, it would have been well within the purview of one having ordinary skill in the art to construct the device as an integral structure with respect to the lid and container for the know and expected result of simplifying the construction of the device. Note, in the absence of unexpected results, the use of a one piece construction instead of separate elements to define a unitary structure is not a patentable distinction (See In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965)).

With respect to claim 36, recitation of the culture medium in the device and/or its orientation fails to structurally device the device over the rejection discussed above because the culture material is considered material worked on and does not further limit the structure of the device (See MPEP 2115).

With respect to claim 38, completing sealing the device would have been well within the purview of one having ordinary skill in the art for the known and expected result of preventing contamination. Note the reference of Friedman et al. discussed above.

6. Claims 11-13, 20 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (US 4,215,198) in view of Calandra et al.(US 5,094,955) alone or further in view of Friedman et al.(US 4,829,005) taken further in view of Greene et al.(US 4,643,197).

The combination of the references Gordon (US 4,215,198) and Calandra et al.(US 5,094,955) alone or alternative further in view of Friedman et al. has been discussed above.

Claims 11-13, 20 and 35 differ by reciting that the inlet and outlet of the device are formed in the lid of the device.

The reference of Greene et al. discloses that it is known in the art to provide both the inlet 38) and outlet (30) of a filter device within the lid structure (26) (See Figure 1).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to employ a filter device as suggested by the reference of Greene et al. for the known and expected result of providing an alternative means recognized in the art to achieve the same result, filter a liquid stream while maintaining the removed particles within the container device holding the filter.

***Response to Arguments***

7. With respect to the rejection of Claims 1-5, 7, 9, 11, 12, 14, 15, 17, 18 and 21 under 35 U.S.C. 103(a) as being unpatentable over Gordon (US 4,215,198) in view of Calandra et al.(US 5,094,955) and Claims 11-13 and 20 under 35 U.S.C. 103(a) as being unpatentable over Gordon (US 4,215,198) in view of Calandra et al.(US 5,094,955) taken further in view of Greene et al.(US 4,643,197), Applicants argue that the combination of the references of Gordon and Calandra et al. are improper because the sensing device of Calandra et al. requires a gas-tight

device and the reference of Gordon is not sealed in a manner that the sensor of Calandra et al. would function.

In response to applicant's argument above, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, while the device of Gordon may not be gas-tight as required when using the sensor of Calandra et al., the Examiner is of the position that one of ordinary skill in the art when using a sensor as suggested by the reference of Calandra et al. would have recognized that the device of Gordon would require gas-tight seals for the sensor to function as intended. Additionally, the reference of Friedman et al. has been cited as evidence that it is conventional in the sterility filtration art to provide the filter containers with gas-tight construction so as to prevent contamination.

Note, the new limitations recited in new claims 29-40 have been addressed in the prior rejections set forth above.

***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner
Art Unit 1797

WHB